IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| IN RE: TRICOR DIRECT PURCHASER ANTITRUST LITIGATION | ) | |
| THIS DOCUMENT RELATES TO: *CVS and Rite Aid* (05-605) | ) | Civil Action No. 05-340 (KAJ) CONSOLIDATED |

**ABBOTT'S ANSWER TO CVS AND RITE AID'S AMENDED COMPLAINT**

Respondent Abbott Laboratories ("Abbott"), by its undersigned attorneys, hereby answers CVS and Rite Aid's ("Plaintiffs") Amended Complaint ("Complaint"), on knowledge as to itself and otherwise on information and belief, as follows:

1. Admit that Defendants manufacture and sell a fenofibrate drug product marketed under the tradename TriCor and that the first sentence of paragraph 1 provides a non-exhaustive description of TriCor. Additionally, Paragraph 1 contains a description of this proceeding and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 1.

2. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 2 and therefore denies them.

3. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 2 and therefore denies them.

4. Admitted.

5. Admitted.

6. Denied.

7. Admit that Plaintiffs purports to bring this action under the identified statutes and that this Court has subject-matter jurisdiction.

8. Admit that venue is proper in this judicial district as to Abbott.

9. Admit that TriCor is sold in interstate commerce. Abbott otherwise denies the allegations in paragraph 9.

10. Paragraph 10 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 10.

11. Paragraph 11 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 11.

12. Paragraph 12 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 12.

13. Paragraph 13 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 13.

14. Paragraph 14 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 14.

15. Paragraph 15 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 15.

16. Paragraph 16 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 16.

17. Denied.

18. Denied.

19. Paragraph 19 contains legal conclusions that require no answer.

20. Paragraph 20 contains legal conclusions that require no answer.

21. Paragraph 21 contains legal conclusions that require no answer.

22. Paragraph 22 contains descriptive narrative and legal conclusions that require no answer.

23. Paragraph 23 contains descriptive narrative and legal conclusions that require no answer.

24. Paragraph 24 contains legal conclusions that require no answer.

25. Paragraph 25 contains legal conclusions that require no answer.

26. Paragraph 26 contains legal conclusions that require no answer.

27. Paragraph 27 contains legal conclusions that require no answer.

28. Paragraph 28 contains legal conclusions that require no answer.

29. Paragraph 29 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 29.

30. Paragraph 30 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 30.

31. Paragraph 31 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 31.

32. Paragraph 32 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 32.

33. Paragraph 33 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 33.

34. Admit that paragraph 34 contains a non-exhaustive description of TriCor.

35. Admit that fenofibrate is a fibrate and that fibrates, statins, bile acid sequestrants, and niacin are cholesterol-lowering drugs. Abbott otherwise denies the allegations in paragraph 35.

36. Admit that fenofibrate has been known to be a cholesterol-lowering agent since at least the early 1980's and that Fournier's fenofibrate-based drug product Lipidil was approved for use in the United States by at least 1993. Abbott otherwise denies the allegations in paragraph 36.

37. Paragraph 37 contains legal conclusions that require no answer. To the extent that Paragraph 37 describes U.S. Patent No. 4,895,726 ("'726 patent"), its prosecution history or its reexamination history, Abbott states that the '726 patent, prosecution history and reexamination history speak for themselves. Abbott otherwise denies the allegations in paragraph 37.

38. Paragraph 38 contains legal conclusions that require no answer. To the extent that Paragraph 38 describes the '726 patent, its prosecution history or its reexamination history, Abbott states that the '726 patent, prosecution history and reexamination history speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 38.

39. Admit that in Fournier filed for reexamination of the '726 patent in December 1999. To the extent that Paragraph 39 describes the reexamination history of the '726 patent, Abbott states that the reexamination history speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 39.

40. Admit that (i) Fournier granted Abbott an exclusive license to the '726 patent in the United States in 1997, (ii) the FDA approved the TriCor 67 mg capsule on February

9, 1998, (iii) the FDA approved TriCor 134 mg and 200 mg capsules on June 30, 1999 and (iv) sales of TriCor exceeded $150 million in 2000 and $250 million in 2001. Abbott otherwise denies the allegations in paragraph 40.

41. Admit that (i) Novopharm filed an ANDA with the FDA on or around December 14, 1999 for fenofibrate capsule, (ii) the ANDA was later amended, and (iii) Novopharm submitted paragraph IV certifications. To the extent that Paragraph 41 describes the ANDA and the paragraph IV certification, Abbott states that the documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 41.

42. Admit that Impax (i) filed an ANDA with the FDA for fenofibrate capsules on or around May 9, 2000 and (iii) submitted paragraph IV certifications. To the extent that Paragraph 42 describes the ANDA and the paragraph IV certification, Abbott states that the documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 42.

43. Admit that Abbott and Fournier filed complaints alleging infringement of the ‘726 patent against Teva and Impax in the United States District Court of the District of Illinois on or about April 7, 2000, August 18, 2000, and March 19, 2001. The complaints speak for themselves and should be read as a whole. Additionally, paragraph 43 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 43.

44. Admit that the FDA granted Impax tentative approval for Impax’s fenofibrate capsules on or around February 20, 2002. Additionally, paragraph 44 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 44.

45. Admit that the Illinois District Court granted summary judgment of non-infringement in favor of Teva and that, on March 20, 2003, the U.S. Court of Appeals for the

Federal Circuit ruled on the appeal of the trial court's decision in *Abbott Laboratories v. Novopharm Ltd.*, 2002 WL 433584 (N.D. Ill. Mar. 20, 2002). Additionally, paragraph 45 contains legal conclusions that require no answer. To the extent Paragraph 45 describes the Illinois District Court opinion in *Abbott Laboratories v. Novopharm Ltd.*, 2002 WL 433584 (N.D. Ill. Mar. 20, 2002) or the Federal Circuit opinion, Abbott states that the opinions speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 45.

46. Admit that (i) Teva received final FDA approval to market its 134 mg and 200 mg fenofibrate capsule product on April 9, 2002, (ii) tentative approval to market its 67 mg fenofibrate capsule product on April 9, 2002 and (iii) final approval to market its 67 mg fenofibrate capsule product on September 3, 2002. Abbott otherwise denies the allegations in paragraph 46.

47. Admit that (i) the Illinois District Court granted Impax's motion for summary judgment on March 26, 2003 and (ii) the FDA granted Impax final approval to market its fenofibrate capsules on September 28, 2003. To the extent that Paragraph 47 describes the District Court's opinion, Abbott states that the opinion speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 47.

48. Denied.

49. Denied.

50. Admit that Abbott obtained FDA approval to market the 54 mg and 160 mg tablet TriCor formulation on September 4, 2001, and that Abbott had previously marketed TriCor capsules. Abbott otherwise denies the allegations in paragraph 50.

51. Admit that Abbott discontinued the TriCor capsule formulation and that Abbott communicated the discontinuance to the public. Abbott otherwise denies the allegations in paragraph 51.

52. Denied.

53. Denied.

54. Admit that TriCor is a maintenance medication. Abbott otherwise denies the allegations in paragraph 54.

55. Admit that Teva received final FDA approval to market its 134 mg and 200 mg fenofibrate capsule product in April 2002. Abbott otherwise denies the allegations in paragraph 55.

56. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 56 regarding what physicians and pharmacies do and therefore denies them. Abbott otherwise denies the allegations in paragraph 56.

57. Admit that Abbott communicated the discontinuance of the TriCor capsule formulation to First Data Bank. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 57 regarding third-party plans and pharmacist practices and therefore denies them. Abbott otherwise denies the allegations in paragraph 57.

58. Admit only that the TriCor tablets (160 mg and 54 mg) are bioequivalent to the TriCor capsules and had common clinical studies. Abbott otherwise denies the allegations in paragraph 58.

59. Admit only that (i) the 160 mg and 54 mg TriCor tablet product contained an indication (HDL) not contained by the TriCor capsule product, (ii) the clinical studies supporting the indication were based on the TriCor capsule product, and (iii) that paragraph 59

purports to reference a FDA document. The document speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 59.

60. Denied.

61. Denied.

62. Denied.

63. Admit that Abbott and Fournier invested resources developing and obtaining FDA approval for the 54 mg and 160 mg TriCor tablet formulations. Abbott otherwise denies the allegations in paragraph 63.

64. Denied.

65. Denied.

66. Denied.

67. Admit that (i) Teva filed an ANDA for 54 mg and 160 mg fenofibrate tablets, (ii) the ANDA contained Paragraph IV certifications for the '726 patent and U.S. Patent Nos. 6,074,670 (the "'670 patent") and 6,277,405 (the "'405 patent"), and (iii) Abbott and Fournier received notice of Teva's Paragraph IV certification on August 21, 2002. Abbott otherwise denies the allegations in paragraph 67.

68. Admit that (i) Teva filed Paragraph IV certifications U.S. Patent Nos. 6,589,552 (the "'552 patent") and 6,652,881 (the "'881 patent"), (ii) Abbott and Fournier received notice of the Paragraph IV certifications, and (iii) Abbott and Fournier filed suit against Teva on the '552 and '881 patents within 45-days after receiving such notice. Abbott otherwise denies the allegations in paragraph 68.

69. Admitted.

70. Paragraph 70 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 70.

71. Admit that (i) Impax filed an ANDA for fenofibrate tablets in or around December 2002, (ii) the ANDA contained Paragraph IV certifications for the '726, '670 and '405 patents, and (iii) Abbott and Fournier filed a complaint against Impax alleging infringement of the '670 and '405 patents on January 23, 2003, and subsequently filed suits alleging infringement of the '552 and '881 patents. Paragraph 71 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 71.

72. Admit that the FDA granted tentative approval to Teva and Impax's ANDA's for 54 mg and 160 mg fenofibrate tablets on March 5, 2004, and that Teva and Impax have represented to this Court that, absent the 30-month stays, they would have received final approval from the FDA on March 5, 2004 and would have entered the market shortly thereafter. Abbott otherwise denies the allegations in paragraph 72.

73. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 73 regarding "likely" actions and therefore denies them. Abbott otherwise denies the allegations in paragraph 73.

74. Admit only that (i) Teva, Impax, Abbott and Fournier agreed to modifications of the original trial schedule, (ii) Abbott and Fournier moved to voluntarily dismiss the patent infringement complaint and Teva's and Impax's counterclaims on May 20, 2005, and (iii) Teva, Impax, Abbott and Fournier jointly stipulated to a dismissal of the patent infringement claims and counterclaims. Abbott otherwise denies the allegations in paragraph 74.

75. Denied.

76. Admit that Abbott and Fournier alleged that Teva and Impax infringed the '726 patent in the Illinois Patent Litigation. Abbott otherwise denies the allegations in paragraph 76.

77. To the extent Paragraph 77 describes the '726 patent, its prosecution history or its reexamination history, Abbott states that the '726 patent, the prosecution history and reexamination history speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 77.

78. To the extent Paragraph 78 describes Novopharm's or Teva's fenofibrate capsule ANDA or paragraph IV certification, Abbott states that the documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 78.

79. Denied.

80. Admit that Paragraph 80 purports to describe the district court and Federal Circuit decisions and quotes from the Federal Circuit decision. Abbott responds that the decisions speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 80.

81. Admits that Paragraph 81 purports to describe the district court opinion in *Abbott Laboratories v. Impax Laboratories, Inc.*, 2003 WL 1563426 (N.D. Ill. 2003), and quotes from the opinion. Abbott responds that the decision speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 81.

82. Admit that Abbott and Fournier initiated the patent infringement action against Teva for infringement of the '726, '670, '405, '552, and '881 patents. Abbott otherwise denies the allegations in paragraph 82.

83. Admit that Teva provided Abbott and Fournier with its Paragraph IV certifications and technical materials from its ANDA. Abbott otherwise denies the allegations in paragraph 83.

84. Denied.

85. Denied.

86. Admit that the '881 patent resulted from Application No. 10/288,425, filed November 6, 2002; and the '881 patent is assigned to Fournier. Admit that Paragraph 86 purports to describe and quotes from the '881 patent. Abbott states that the patent and its prosecution history speak for themselves. Abbott otherwise denies the allegations in paragraph 86.

87. Admit that Fournier is the owner of the '726 patent and that paragraph 87 purports to describe the '726 patent. Abbott states that the '726 patent, its prosecution history and its reexamination history speak for themselves and should be read as a whole. Paragraph 87 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 87.

88. Admit that paragraph 88 purports to describe the '881 patent and quotes from it. Abbott states that the '881 patent and its prosecution history speak for themselves and should be read as a whole. Paragraph 88 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 88.

89. Admit that paragraph 89 purports to describe the '881 prosecution history and quotes from it. Abbott states that the '881 patent and its prosecution history speak for themselves and should be read as a whole. Paragraph 89 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 89.

90. Admit that paragraph 90 purports to describe the ‘881 prosecution history and quotes from it. Abbott states that the ‘881 patent and its prosecution history speak for themselves and should be read as a whole. Paragraph 90 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 90.

91. Admitted.

92. Paragraph 92 contains legal conclusions that require no answer. To the extent paragraph 92 describes the ‘881 prosecution history, Abbott states that the ‘881 patent and its prosecution history speak for themselves. Abbott otherwise denies the allegations in paragraph 92.

93. Paragraph 93 contains legal conclusions that require no answer. Abbot admits only that paragraph 93 purports to describe the ‘881 patent or its prosecution history. Abbott states that the ‘881 patent and its prosecution history speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 93.

94. Paragraph 94 contains legal conclusions that require no answer. Admit only that Paragraph 94 purports describe unspecified Fournier documents. Without a cite to a specific document, Abbott is without sufficient knowledge or information to form a belief as the to the truth of the allegations in paragraph 94 and therefore denies them. Abbott otherwise denies the allegations in paragraph 94.

95. Admit only that paragraph 95 purports to describe the prosecution history of the ‘881 patent. Abbott states that the ‘881 patent and its prosecution history speak for themselves and should be read as a whole. Additionally, paragraph 95 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 95.

96. Admit only that paragraph 96 purports to describe the prosecution history of the '881 patent. Abbott states that the '881 patent and its prosecution history speak for themselves and should be read as a whole. Additionally, paragraph 96 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 96.

97. Admit only that paragraph 97 purports to describe the prosecution history of the '881 patent. Abbott states that the '881 patent and its prosecution history speak for themselves and should be read as a whole. Additionally, paragraph 97 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 97.

98. Paragraph 98 contains legal conclusions that require no answer.

99. Paragraph 99 contains legal conclusions regarding the "duty to disclose" and "material information" that require no answer. Admit only that Reginault signed an inventor's oath in connection with the '726 patent. Abbott states that the inventor's oath, and the '881 patent and its prosecution history speak for themselves and should be read as a whole. Abbott is without sufficient knowledge or information to form a belief as to Reginault's "aware[ness]" as alleged in paragraph 99 and therefore denies this allegation. Abbott otherwise denies the allegations in paragraph 99.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

104. Admit that Abbott obtained FDA approval on November 5, 2004, to market a new TriCor tablet formulation that contains the same active ingredient, fenofibrate, in 48 mg and 145 mg strengths. Abbott otherwise denies the allegations in paragraph 104.

105. Admit that (i) the new 48 and 145 mg tablet formulations allow patients to take TriCor without meals, and were developed using patented nanotechnology licensed from Elan Corporation, Plc, and (ii) the patent license obtained from Elan was exclusive for the field of fenofibrate dosage forms. Abbott otherwise denies the allegations in paragraph 105.

106. Admit that Abbott discontinued the TriCor original tablet formulation when the new tablet formulation became available and communicated the tablet discontinuance to First Data Bank and to the public. Abbott otherwise denies the allegations in paragraph 106.

107. Admit only that Abbott under certain circumstances accepted returns of the original tablet formulation. Additionally, paragraph 107 purports to describe unspecified Abbott documents. Without cites to specific documents, Abbott is without sufficient knowledge or information to form a belief as the to the truth of the allegations in paragraph 107 and therefore denies them. Abbott otherwise denies the allegations in paragraph 107.

108. Denied.

109. Denied.

110. Denied.

111. Denied.

112. Admit that the relevant geographic market is the United States. Abbott otherwise denies the allegations in paragraph 112.

113. Denied.

114. Denied.

**COUNT I**

**MONOPOLIZATION (15 U.S.C. § 2)**

115. Abbott incorporates by reference the responses contained in paragraphs 1 through 114 above.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

120. Denied.

## COUNT II

### CONSPIRACY IN RESTRAINT OF TRADE (15 U.S.C. § 1)

121. Abbott incorporates by reference the responses contained in paragraphs 1 through 120 above.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

## ADDITIONAL DEFENSES

FIRST ADDITIONAL DEFENSE

Plaintiffs fail to state a claim against Abbott upon which relief may be granted.

SECOND ADDITIONAL DEFENSE

Plaintiffs have not suffered, and will not suffer, injury of the type that the antitrust laws are designed to prevent, or any other injury to a legally cognizable interest, by reason of the conduct alleged in the Complaint.

THIRD ADDITIONAL DEFENSE

At all times, Abbott has acted in good faith in furtherance of its legitimate business interests and has caused no injury to competition, the public, or plaintiffs.

FOURTH ADDITIONAL DEFENSE

Abbott's conduct is protected under the Noerr-Pennington doctrine and/or otherwise under the Constitution of the United States.

FIFTH ADDITIONAL DEFENSE

Plaintiffs' claims are precluded, in whole or in part, by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984 and related amendments.

SIXTH ADDITIONAL DEFENSE

To the extent there is a finding of conduct that prevented generic entry and higher prices as a result, plaintiffs' claims are barred, in whole or in part, to the extent any higher prices were passed on, in whole or in part, to parties not included in this action.

SEVENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs would be unjustly enriched if allowed to recover all or any part of the damages alleged in the Complaint.

EIGHTH ADDITIONAL DEFENSE

Plaintiffs' claims fail to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

NINTH ADDITIONAL DEFENSE

Plaintiffs did not suffer injury or damages by reason of any act or omission by Abbott.

TENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs failed to mitigate their damages.

ELEVENTH ADDITIONAL DEFENSE

Any injuries, losses, or damages suffered by plaintiffs were proximately caused by their own actions regardless of whether contributory, negligent, incompetent, careless or reckless.

TWELFTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs alleged damages, if any, are speculative.

THIRTEENTH ADDITIONAL DEFENSE

Abbott does not maintain monopoly power in the relevant market.

FOURTEENTH ADDITIONAL DEFENSE

The Food and Drug Administration approved each version of TriCor for sale in the United States.

FIFTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because they contravene the rule of law established by the United States Supreme Court in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) .

SIXTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations and/or laches.

SEVENTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because of waiver and/or estoppel.

EIGHTEENTH ADDITIONAL DEFENSE

Abbott reserves the right to add to its additional defenses as additional information becomes available in the course of this litigation.

**RELIEF REQUESTED**

WHEREFORE, Abbott, having answered, respectfully requests judgment dismissing with prejudice the CVS and Rite Aid Complaint and each and every claim for relief therein, and awarding Abbott its costs, disbursements, attorneys' fees and such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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Dated: July 21, 2006
529727

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on July 21, 2006, the foregoing were caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on July 21, 2006 upon the following parties:

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The undersigned also hereby certifies that on July 21, 2006, true and correct copies of the foregoing were caused to be served by hand upon the following local counsel:

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